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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,902	01/09/2002	Edward Nowak	3399-4006	9768

7590

05/01/2003

Morgan & Finnegan
345 Park Avenue
New York, NY 10154

EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,902

Applicant(s)

NOWAK ET AL.

Examiner

Humera N. Sheikh

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 31/2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Application

Receipt is acknowledged of the Preliminary Amendment and the Prior Art filed 01/09/02, the Transmittal Letter filed 03/01/02 and the Correction of Filing Receipt filed 04/03/02.

Claims 15-47 are pending. Claims 1-14 have been cancelled. Claims 15-47 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (WO 97/35537).

Brown discloses capsules, a method of encapsulation and an encapsulation apparatus, wherein the capsules comprise metered doses of substances to be encapsulated within the capsule, wherein as the doses of substances are injected between the heated films, the films deform to line the indentations, forming series of

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pairs of opposed capsule halves containing the substance. The pairs of capsule halves are then brought together, sealed and cut, thus forming capsules containing the substance.

The method of encapsulation is characterized by supplying to an encapsulation unit, two films of like material capable of deforming elastically at least when partially solvated, and applying solvent to at least one of the films prior to encapsulation to cause partial solvation of the material surface, such that the partially solvated surface can adhere to and seal with the film material. The invention enables encapsulation using materials other than gelatin, such as polyvinyl alcohol. Further suitable materials include alginate, hydroxypropyl methyl cellulose and polyethylene oxide, for example (see page 6, lines 5-19 and Abstract).

Claims 15, 16, 19, 20, 28-29, 31, 35-36, 38, 42, 43 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda et al. (EPO 0 211 079 A1).

Ueda discloses a soft multi-chamber delivery capsule, process of making and an apparatus for producing the capsule, wherein the capsule consists of a covering, the inner space of which is divided into a plurality of chambers by at least one partition. The number of such chambers is usually two, and the space between the first and second coverings is divided into two chambers by a partition provided therebetween. The capsule comprises a first, second and third film, whereby the films are joined under

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pressure, except their respective capsule-defining portions. The chambers contain materials, such as medicine, cosmetics or food (see Abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17, 18, 21-27, 30, 32-34, 37, 39-41 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. (EPO 0 211 079 A1) in view of Brown (WO 97/35537).

Ueda, as discussed above, teaches a soft multi-chamber delivery capsule, process of making and an apparatus for producing the capsule, wherein the capsule consists of a covering, the inner space of which is divided into a plurality of chambers by at least one partition. The number of such chambers is usually two, and the space

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between the first and second coverings is divided into two chambers by a partition provided therebetween. The capsule comprises a first, second and third film, whereby the films are joined under pressure, except their respective capsule-defining portions. The chambers contain materials, such as medicine, cosmetics or food (see Abstract).

Ueda teaches a soft capsule of novel structure, which, although single, is adapted to stably enclose at least two kinds of incompatible contents, and which can be made, for example, to have one portion of rapidly soluble or intragastrically soluble properties and the other portion of prolonged release or enteric properties, or to have one portion with a rapid release action and the other portion with a delayed release action. With the multicellular soft capsule, different contents can be enclosed in the different cells (page 2, lines 15-23).

Any material usually used for the shell of the soft capsules is usable for forming the shells and partition, such as gelatin, plasticizers, perfume, pigments, solubility, adjusting agents, etc. can be added as desired (pg. 11, lines 6-11).

The multicellular capsule may be of any shape, such as oval shape, oblong form, round form, tubular form or in the form of a suppository (pg. 11, lines 16-21).

The examples on pages 13-17 demonstrate the method of manufacturing the multicellular soft capsules.

Ueda is deficient only in the sense that he does not explicitly teach chambers containing metered doses of materials contained within the capsule.

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Brown teaches capsules comprising metered doses of substances to be encapsulated within the capsule, carried out through injection, wherein as the doses of substances are injected between the heated films, the films deform to line the indentations, forming series of pairs of opposed capsule halves containing the substance (see page 6, lines 5-19).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of *Brown* within the teachings of *Ueda*, because *Brown* teaches capsules comprising metered doses of substances contained within the capsule and similarly *Ueda* teaches multicellular capsules comprising various amounts of different materials within the capsule. The expected result would be an improved multicellular capsule comprising metered doses of varying substances for effective capsule delivery.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns

April 28, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600